

NDA 19-452/S-015

Hill Dermaceuticals, Inc.  
Attention: Jerry S. Roth  
President  
2650 South Mellonville Avenue  
Sanford, Florida 32773

Dear Mr. Roth:

Please refer to your supplemental new drug application dated August 13, 1998, received August 18, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Derma-Smoothe/FS Topical Oil, 0.01%.

We acknowledge receipt of your submissions dated August 28, September 18 (two), and 30, and November 24, 1998; January 12, and 26, March 1, 10, and 26, April 6, May 5, 14, 21, and 27, June 8, and 10, and July 8, and 19, and August 12, and 17, 1999.

This supplemental new drug application provides for the use of Derma-Smoothe/FS Topical Oil, 0.01% for the treatment of atopic dermatitis in pediatric patients 6 years of age or older.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed agreed upon labeling text for the package insert and immediate container labels. Marketing the product with FPL that is not identical to the agreed upon labeling text and container labels may render the product misbranded.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 19-452/S-015." Approval of this submission by FDA is not required before the labeling is used.

We remind you of your Phase 4 commitment specified in your facsimile dated August 17, 1999. These commitments, along with any completion dates agreed upon, are listed below.

1. To conduct a Phase 4 clinical trial evaluating local safety on the face in children with atopic dermatitis. Clinical assessments will include a focused evaluation of local cutaneous adverse events such as skin atrophy, skin pigmentation changes, telangiectasis, shininess, thinness, striae, bruising, loss of elasticity, and loss of normal skin markings within 8 months of approval.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2  
FDA  
5600 Fishers Lane  
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Millie Wright, Project Manager, at (301) 827-2020.

Sincerely,

Jonathan K. Wilkin, M.D.  
Director  
Division of Dermatologic and Dental Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research